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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE

CV 12- 6360 KAW

LIFESCAN, INC. and JOHNSON & JOHNSON,

Plaintiffs,

vs.

SHASTA TECHNOLOGIES, LLC, DECISION DIAGNOSTICS CORP., PHARMATECH SOLUTIONS, INC., and CONDUCTIVE TECHNOLOGIES, INC.,

Defendants.

Case No.

COMPLAINT

(Demand for Jury Trial)

Plaintiffs LifeScan, Inc. ("LifeScan") and Johnson & Johnson ("Johnson & Johnson") (collectively "Plaintiffs") hereby file this Complaint against Defendants Shasta Technologies, LLC ("Shasta"), Decision Diagnostics Corp. ("DDC") (formerly known as InstaCare Corp.), PharmaTech Solutions, Inc. ("PharmaTech"), and Conductive Technologies, Inc. ("Conductive") (collectively the "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This action seeks injunctive relief, declaratory relief, and damages in connection with Defendants' misappropriation of the substantial goodwill Plaintiffs have developed in their LifeScan and OneTouch® Ultra® brands to promote Defendants' competing product, the Shasta GenStrip. Defendants make unauthorized use of Plaintiffs' trademarks and trade dress in their product packaging and advertising to falsely convey that LifeScan endorses use of the GenStrip with its products, in violation of federal and state law. Defendants also make false claims in their advertising and infringe Plaintiffs' trademarks in violation of federal and state law.

2. Plaintiff LifeScan is the long-established, market-leading manufacturer and seller of blood glucose monitoring systems, which consist of blood glucose meters and test strips. Its meters and test strips are sold under the OneTouch® Ultra® brand name (the "OneTouch Ultra products").

3. OneTouch Ultra products have been on the market since 2001, and more than 5 million individuals with diabetes in the United States use OneTouch Ultra products today. The OneTouch Ultra brand is synonymous with reliability and ease of use. It is the brand most recommended by primary care physicians and endocrinologists in the United States.

4. Defendants have developed a blood glucose test strip, GenStrip, to be used with LifeScan's meters. Because GenStrip infringes patents owned by LifeScan Scotland Limited, on September 9, 2011, LifeScan and LifeScan Scotland brought a patent infringement action against Defendants in connection with the GenStrip product. *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 11-cv-4494-EJD (N.D. Cal.). That case is currently in discovery.

5. While the patent litigation has been pending, Defendants have continued the process of obtaining FDA clearance to market the GenStrip. That clearance was granted on November 30, 2012.

6. The FDA has cleared GenStrip for use only with certain OneTouch Ultra meters: OneTouch® Ultra®, OneTouch® Ultra® 2, and OneTouch® UltraMini® meters purchased before July 2010. (Exhibit 1 (FDA clearance letter).)

7. On information and belief, GenStrip is the first propriety product that Defendants have brought to market. Because Defendants have never before marketed a product under the Shasta or GenStrip names, they have, as yet, no goodwill or reputation with consumers who use blood glucose monitor systems.

8. Rather than build their own reputation and goodwill, Defendants' advertising makes prominent and unnecessary use of Plaintiffs' trademarks and trade dress to falsely convey to consumers that LifeScan endorses use of the GenStrip with its products. Most notably, Defendants' packaging for the GenStrip product prominently features an image of LifeScan's most distinctive and widely used meter, the OneTouch UltraMini. Defendants also make false claims concerning the scope of their FDA clearance, falsely conveying to consumers that the GenStrip is cleared for use with more LifeScan OneTouch Ultra meters than is actually the case.

9. If Defendants are permitted to engage in such bad faith, anti-competitive conduct, Plaintiffs' market share and hard-earned reputation and goodwill will be seriously, and irreparably, damaged.

THE PARTIES

10. Plaintiff LifeScan is a corporation organized under the laws of the State of California, having its headquarters and principal place of business at 1000 Gibraltar Drive, Milpitas, California 95035. LifeScan is a wholly owned operating subsidiary of Plaintiff Johnson & Johnson.

11. Plaintiff Johnson & Johnson is a corporation organized under the laws of the State of New Jersey, having its headquarters and principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

12. On information and belief, Shasta is a corporation organized under the laws of the State of Oregon, having a principal place of business at 7340 Hunziker Road, Suite 205, Tigard,

Oregon 97223.

13. On information and belief, DDC is a corporation organized under the laws of the State of Nevada, having a principal place of business at 2660 Townsgate Road, Suite 300, Westlake Village, California 91361. DDC formerly was known as InstaCare Corp. ("InstaCare").

14. On information and belief, PharmaTech is a corporation organized under the laws of the State of Nevada, having a principal place of business at 2660 Townsgate Road, Suite 300, Westlake Village, California 91361.

15. On information and belief, Conductive is a corporation organized under the laws of the State of Pennsylvania, having a principal place of business located at 935 Borom Road, York, Pennsylvania, 17404.

JURISDICTION AND VENUE

16. This Court has jurisdiction over Plaintiffs' federal claims pursuant to 28 U.S.C. §§ 1331 and 1338, and has supplemental jurisdiction over Plaintiffs' state law claims under 28 U.S.C. § 1367.

17. On information and belief, this Court has personal jurisdiction over Shasta because Shasta has had continuous, systematic, and substantial contacts with the State of California, including doing business in this judicial district and having a place of business within this judicial district at 3257 Highway 128, Calistoga, California 94515.

18. On information and belief, this Court has personal jurisdiction over DDC because DDC has had continuous, systematic, and substantial contacts with the State of California, including doing business in this judicial district and having a principal place of business within the State of California at 2660 Townsgate Road, Suite 300, Westlake Village, California 91351.

19. On information and belief, this Court has personal jurisdiction over PharmaTech because PharmaTech has had continuous, systematic, and substantial contacts with the State of California, including doing business in this judicial district and having a principal place of business with the State of California at 2660 Townsgate Road, Suite 300, Westlake Village, California 91351.

20. On information and belief, this Court has personal jurisdiction over Conductive because Conductive has had continuous, systematic, and substantial contacts with the State of California, including regularly doing business in this judicial district, and has entered into a contract with Shasta, DDC, and/or PharmaTech to supply products in into this judicial district.

21. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

LifeScan's OneTouch Ultra Systems

22. People with diabetes use glucose monitoring systems to self-monitor their blood glucose levels. This self-monitoring is one of the most important things diabetic patients can do to manage their disease and prevent long-term complications. Using these systems, a person with diabetes can determine if his or her blood glucose is abnormally low or abnormally high, requiring management.

23. LifeScan sells blood glucose monitoring systems under the OneTouch® Ultra® brand. The OneTouch Ultra family of glucose monitors includes the OneTouch® Ultra®, OneTouch® Ultra® 2, OneTouch® UltraSmart®, OneTouch® UltraLink®, OneTouch® Ping®, and OneTouch® UltraMini®. These monitors are designed for use with OneTouch® Ultra® glucose test strips.

24. To use LifeScan's OneTouch Ultra system, a person inserts a OneTouch Ultra test strip into the port of a OneTouch Ultra meter. The person then pricks his or her finger or forearm with a lancet to obtain a small blood sample, and places a drop of blood on the test strip. The meter determines the blood glucose level in the sample by measuring the flow of electrical current. Within seconds, the meter displays the person's blood glucose level as a number on a digital display. Based on this reading, the person may determine if his or her blood glucose level is within a satisfactory range or if some intervention or treatment is required to raise or lower the blood glucose level.

25. LifeScan's OneTouch Ultra systems are an extremely successful product. LifeScan had over $1 billion in sales of OneTouch Ultra products in the United States in 2011, and is on pace to sell nearly $1 billion of OneTouch Ultra products in the United States in 2012.

26. The OneTouch Ultra products lead the market, which is composed of LifeScan and its three major competitors – Abbott Diabetes Care (which sells under the FreeStyle brand), Roche Diagnostics (which sells under the Accu-Check brand), and Bayer Corporation (which sells under the Contour brand) – plus private labels such as Wal-Mart and Walgreens. The four major competitors have approximately 83% of the total United States market. Of them, LifeScan has by far the largest market share, with more than a 30% share of the total United States market.

27. Each competitor in the United States blood glucose monitor market distributes its own glucose meters and test strips that work with that particular company's meters. Their test strips are not compatible with OneTouch Ultra meters and cannot be used with them. Similarly, LifeScan's OneTouch Ultra test strips are not compatible with those companies' glucose meters.

LifeScan's Investment in the OneTouch Brand

28. LifeScan has made an enormous investment in the OneTouch brand, and actively and continuously invests in and protects the goodwill associated with the brand.

29. Johnson & Johnson or LifeScan (before it was acquired by Johnson & Johnson) registered the words used in the names of each of the several LifeScan OneTouch Ultra meters, including: "LifeScan" (Reg. No. 1,384,863), "OneTouch" (Reg. No. 2,863,393), "One Touch" (Reg. No. 1,484,999), "Ultra" (Reg. No. 3,642,309), and "UltraMini" (Reg. No. 3,442,347). All of these words are protected with respect to use with both blood glucose monitors and the related test strips. (Exhibit 2.)

30. LifeScan has used the OneTouch and Ultra marks for more than a decade, since January 2001.

31. LifeScan has a sales force of more than 225 employees who promote OneTouch Ultra products to healthcare professionals.

32. In addition, LifeScan has spent over $100 million over the last decade promoting its OneTouch Ultra brand to consumers.

33. LifeScan has also invested in the OneTouch brand by creating the visually distinctive OneTouch UltraMini meter, which Defendants have chosen to feature on their own

product packaging and in their advertising.

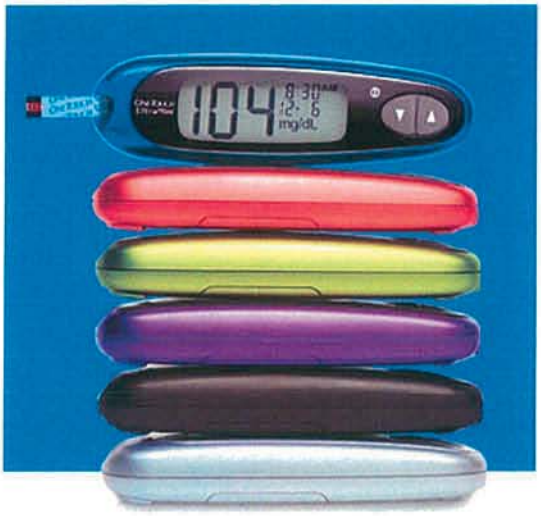
34. The OneTouch UltraMini, which launched in September 2006, is LifeScan's best-selling blood-glucose meter. It was the top meter in the market in 2012, with a 17% market share of meters shipped to retailers and wholesalers.

35. LifeScan developed the OneTouch UltraMini to offer consumers an attractive and affordable blood-glucose meter. At launch, LifeScan offered the OneTouch UltraMini in silver, and added five additional colors by late 2008.

36. The OneTouch UltraMini meter is a distinctively small, slender, and sleek device, horizontally oriented, with rounded corners, and available in vibrant colors unique in the blood-glucose monitor market: Limelight®, Pink Glow®, Silver Moon®, Jet Black®, Purple Twilight®, and Blue Comet®. On the face of the UltraMini are the words "OneTouch" and, underneath that, "UltraMini," all in white lettering and written in the same distinctive font and style as the brand names on LifeScan's other glucose monitors:

37. The UltraMini's distinctive appearance is an important feature that LifeScan emphasizes in its advertising. LifeScan's web page for the OneTouch UltraMini (http://www.onetouch.com/onetouch-ultramini (last visited December 13, 2012)) emphasizes the OneTouch UltraMini's shape and size with the tagline: "It's sleek, simple to use and perfect for on the go." (Exhibit 3 (also includes http://www.onetouch.com/onetouch-ultramini/tour (last visited December 13, 2012)).) The dominant image on the OneTouch UltraMini's homepage is a stack of six slim UltraMini meters, in each of the available colors, forming a rainbow effect (shown below),

and the text also emphasizes that the OneTouch UltraMini "Comes in 6 great colors":



- **Colorful**
  Comes in 6 great colors—Limelight®, Pink Glow®, Silver Moon®, Jet Black®, Purple Twilight® and Blue Comet®

38. The OneTouch UltraMini is extremely well-regarded by consumers. A 2007 market-research analysis conducted approximately a year after the product launch concluded that 91% of users were highly satisfied or completely satisfied with their OneTouch UltraMini meters, and 97% of customers indicated that they definitely or probably would recommend the OneTouch UltraMini to another person with diabetes.

39. The same 2007 analysis also found that consumers ranked the appearance of the OneTouch UltraMini – including its shape, color, and size – as the three most important reasons for purchasing this meter.

40. The OneTouch UltraMini's unique combination of elements – the name OneTouch UltraMini; the color, font, and style of the letters; and the distinctive shape, appearance, and color of the device – do not serve any function other than to identify LifeScan's OneTouch UltraMini product, and have acquired a secondary meaning in the marketplace.

The Introduction of Defendants' GenStrip

41. On November 30, 2012, Shasta received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") to sell a test strip for glucose diagnostics under the name "Shasta GenStrip." The Shasta GenStrip is designed to work with certain OneTouch Ultra meters as a

substitute for LifeScan's OneTouch Ultra test strips.

42. On information and belief, Shasta and PharmaTech have entered an agreement regarding the control, management, and distribution of Shasta GenStrip, including distribution within the United States.

43. On information and belief, Shasta, PharmaTech, and/or DDC have entered an agreement with Conductive regarding the manufacture of Shasta GenStrip, including for distribution within the United States.

44. Defendants' entry into the test strip market is imminent. In a telephone call for investors on December 11, 2012 (a transcript of which is attached as Exhibit 4), Keith Berman, President and Chief Financial Officer of DDC, said that Shasta would "hit the ground running" in terms of sale and distributions in January 2013, and that there were already "substantial orders from large regional distributors" and a "distribution contract with Walmart." (*Id.* at 11.)

45. The FDA's clearance of Defendants' GenStrip product was limited. The FDA only cleared GenStrip test strips for use with LifeScan glucose meters purchased *before July 2010*. (Exhibit 1.)

46. In addition, the "Indications for Use" that accompany the FDA's November 30 clearance letter indicate that GenStrips are cleared for use with only three of the Ultra-brand meters (purchased before July 2010): the OneTouch® Ultra®, Ultra®2 and UltraMini® Meters. (*Id.*).

47. Further, the FDA's letter states that the clearance is only for "GenStrip™ Test Strips with calibration codes 4, 10, and 13."

48. The calibration code limitation is significant because LifeScan's OneTouch Ultra meters can be set to different calibration codes, depending on the glucose test strip being used. There are 49 possible codes.

49. Since 2009, LifeScan has sold test strips in the United States with only one calibration code: 25. Moreover, for the past three years, all of the OneTouch Ultra meters sold by LifeScan have been pre-set to calibration code 25 in order to produce accurate results. Thus, since 2009, owners of OneTouch Ultra meters have had no reason to reset their calibration codes.

50. If a customer uses strips with a calibration code other than calibration code 25

(for example, the calibration codes for which the GenStrip has received clearance) without resetting his or her OneTouch Ultra meter to the strips' calibration code, there would be a mismatch between calibration codes for the meter and the strips.

51. There is no suggestion that the Shasta GenStrip could be used with glucose meters supplied by any company other than LifeScan, and the FDA has not cleared the GenStrip for use with other companies' meters.

Defendants' Advertising Falsely Implies That LifeScan Endorses the GenStrip

52. Defendants have already commenced advertising the GenStrip on the internet, and have done so in a manner that attempts to misappropriate the enormous goodwill associated with LifeScan and its OneTouch brand.

53. GenStrip will be the first electrochemical glucose test strip sold in the United States that is made by a company other than the company making the glucose meter.

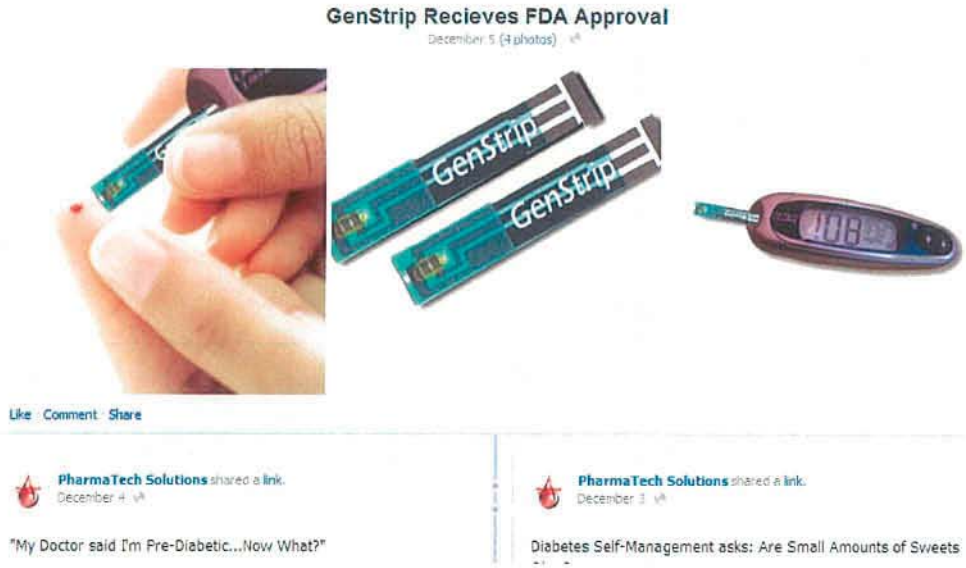
54. Consumers, based on their experience, are predisposed to believe that a company that produces glucose test strips is associated with the company that produces their glucose monitors. Not only do Defendants do nothing to dispel this pre-existing assumption, they exploit and encourage it through their unauthorized and unnecessary use of the LifeScan, OneTouch, and UltraMini trademarks and the UltraMini trade dress.

55. Defendants' advertising to date consists of four websites: Pharmatech's (http://www.pharmatechdirect.com/genstrip.html (last visited December 13, 2012) (the "PharmaTech Website") (Exhibit 5)), Shasta's (http://shastagenstrip.com and http://shastagenstrip.com/genstrip.html (both last visited December 13, 2012) (the "Shasta Website") (Exhibit 6)), DDC's (http://www.decisiondiagnostics.com/genstrip.html (last visited December 13, 2012) (the "DDC Website") (Exhibit 1, to which the FDA letter is attached)), and PharmaTech's Facebook page (https://www.facebook.com/PharmaTechSolutions (last visited December 13, 2012) (the "PharmaTech Facebook Page") (Exhibit 7)) (together, "the Websites").

56. The Shasta and PharmaTech Websites and the Pharmatech Facebook Page include images that, on information and belief, show the front of the package and vial in which Defendants intend to sell the GenStrip product.

57. Both the package and the vial label feature, as their most prominent design element, a photograph of LifeScan's distinctive OneTouch UltraMini meter in the Purple Twilight® color, with the OneTouch UltraMini trademarked name visible, being used with a GenStrip:

58. In addition, the PharmaTech Facebook Page includes an image that displays the entire OneTouch UltraMini meter in Purple Twilight®:

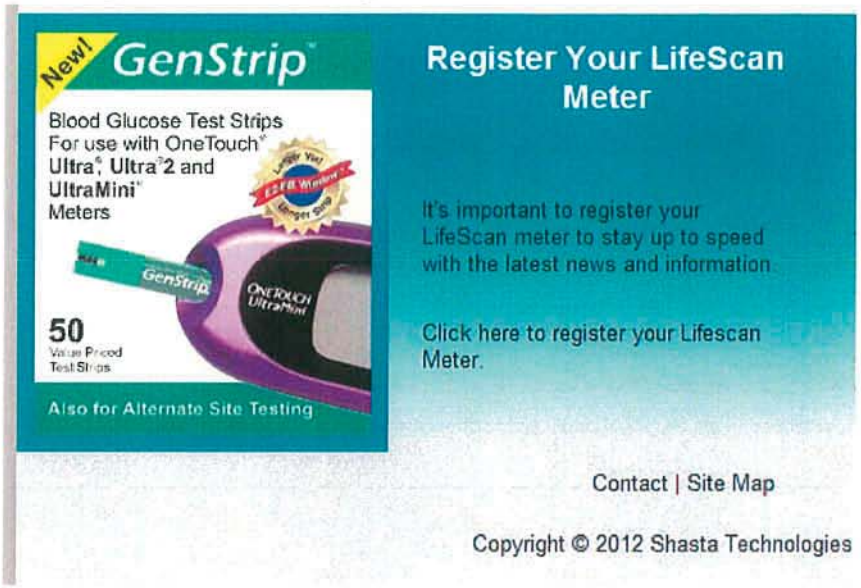


59. Defendants could have simply named in their advertising the OneTouch Ultra meters with which the GenStrip has been cleared for use. Instead, they did far more. The prominence of the image of the OneTouch UltraMini (including its logo, which uses the registered trademarks "OneTouch" and "UltraMini") on GenStrip's package and vial label, and on the Shasta and PharmaTech Websites, falsely conveys that LifeScan endorses the use of its meters with the GenStrip test strips.

60. Defendants added to the message of endorsement by picturing what appears to be a "seal of approval" directly above the image of the OneTouch UltraMini device.

61. Defendants did not include any disclaimer of affiliation with LifeScan on the GenStrip packaging or on the websites, confirming their intent to convey that LifeScan endorses the use of the GenStrip with its products.

62. Indeed, adding to the false message that LifeScan endorses use of the GenStrip, the Shasta GenStrip website unnecessarily makes repeated use of LifeScan's name. Further, immediately underneath and next to images of the package showing the OneTouch UltraMini, the website urges consumers to register their LifeScan meters:



63. The link provided by Defendants, over the words "Click here to register your *LifeScan* Meter" (emphasis added), brings users to LifeScan's "OneTouch® Product Registration" website (https://www.onetouch.com/product-registration (last visited December 13, 2012) (Exhibit 8)). This literal link to LifeScan both unnecessarily uses the LifeScan trademark and further implies LifeScan's affiliation with, and endorsement of, the GenStrip product.

64. And while Defendants, on the Websites, make certain competitive statements (discussed below), they do not specifically refer to LifeScan in these statements, instead using terms such as "Branded product." This heightens the impression that the GenStrip is in fact affiliated with and endorsed by LifeScan.

65. Even consumers who do not use the OneTouch UltraMini meter, and instead use a different OneTouch Ultra meter, will immediately recognize the image on GenStrip's packaging due to the use of the OneTouch Ultra logo – which has been the same since 2001; the OneTouch UltraMini's distinctive appearance; LifeScan's extensive advertising for the UltraMini; and the fact that the UltraMini (along with other Ultra meters) is depicted on the packages for Ultra-brand test strips used with all Ultra meters.

LifeScan Does Not Endorse the GenStrip Brand

66. Contrary to Defendants' false message, LifeScan has in no way given its approval or endorsement to the GenStrip product. The opposite is true. As the packaging of OneTouch Ultra meters warns, "[t]he accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan." (Exhibit 9.)

67. Johnson & Johnson and LifeScan have not given Defendants permission to use their trademarks or trade dress in Defendants' advertising.

Defendants' Advertising Includes Literally False Statements

68. In addition to falsely conveying that LifeScan endorses and approves of the use of GenStrip with its products, the Websites and label for the GenStrip vial also contain numerous literally false statements.

69. The Websites and vial label falsely state that the FDA has cleared the GenStrip for more uses than is actually the case. The vial label depicted on the Shasta and PharmaTech Websites states, in large font, "For use with *all* OneTouch® ULTRA® Meters" (emphasis added).

70. The DDC and PharmaTech Websites also separately state that the GenStrip was cleared "[f]or use with LifeScan One Touch® Ultra®, Ultra 2®, Ultra Smart® and Ultra Mini® meters."

71. These claims are literally false. The GenStrip is not cleared for use with "all" OneTouch Ultra meters. The FDA's November 30 letter makes clear that: (1) the GenStrip is cleared for use only with certain Ultra, Ultra 2, and UltraMini meters – but not the UltraSmart, UltraLink, or OneTouch Ping meters; and (2) even with respect to Ultra, Ultra 2, and UltraMini meters, the GenStrip is cleared for use only with meters purchased before July 2010.

72. These false claims are highly material to consumers, because a consumer would not purchase the GenStrip unless he or she believed it could be used with his or her Ultra-brand meter.

73. Further, the Shasta Website states that each OneTouch Ultra meter "has a unique and prominent serial number" that allows users to look up the meter's date of manufacture on a chart provided by Shasta (Exhibit 10), in order to determine compatibility with the GenStrip. This implies that the date of manufacture is the relevant date. In fact, the FDA has cleared GenStrip for use based on the date of *purchase*. An indeterminate number of meters manufactured before July 2010 were purchased after July 2010, and thus are not cleared for use with the GenStrip. Thus, contrary to Shasta's statements, compatibility cannot be determined simply by looking at the date of manufacture. Moreover, by focussing on the date of manufacture, the Shasta Website confuses customers about the actual scope of the FDA clearance.

74. The PharmaTech Website also claims that GenStrip provides "increased accuracy."

Features for Diabetics

- Requires just a speck of blood
- Results in as little as 5 seconds
- Easy to see when there is enough blood
- Increased accuracy

75. The PharmaTech Website adds, "Frequent, accurate results leads to *better* results" (emphasis added).

Benefits

You have enough to worry about, the cost of diabetic testing supplies shouldn't be one of them.

- The convenience of low cost helps in managing diabetes
- Small blood sample required means less pain
- Frequent, accurate results leads to better results and better informed lifestyle decisions
- Affordability of test strips means you can worry less about money and concentrate about what's more important -- your health

76. Defendants' claim that consumers of GenStrips will enjoy "increased accuracy" and "better results" – presumably in comparison to already existing glucose test strips – is contradicted by the FDA's clearance letter, which states that the GenStrips are "substantially equivalent" to previously available glucose test strips. On information and belief, it is false that GenStrips are more accurate or provide better results, in any clinically meaningful sense, than other available glucose test strips, including OneTouch Ultra.

77. Finally, the very name "GenStrip" falsely implies that Defendants are selling a "generic" product that can be used across various glucose monitoring platforms. In fact, the GenStrip is not a "generic" product at all, since its use is narrowly limited to a set of LifeScan's OneTouch Ultra meters. Further, to the extent that the name "GenStrip" implies that the product is "generic" and can be substituted for genuine OneTouch Ultra test strips manufactured by LifeScan (just as a generic drug can be substituted for a brand-name equivalent), the implication is also false.

GenStrip cannot be substituted for genuine OneTouch Ultra test strips, which are not limited in their use in the same manner that GenStrip's indication is limited.

78. In fact, Keith Berman, President and CFO of DDC, has admitted, and indeed insisted, that GenStrips – contrary to the clear implication of their name – are not a "generic" product. In an interview with an online diabetes newsletter, reported on December 13, 2012 (http://www.diabetesmine.com/2012/12/new-generic-test-strips-may-be-better-than-originals.html (last visited December 13, 2012) (Exhibit 11)), Berman emphasized that GenStrips are "not *'generic.'*" (emphasis in original). He added: "A generic is an indication that your product is exactly the same as the one it's based off of. This isn't. It's an independently developed diagnostic product, an alternative. It's the same product for half the price, and a little better." (*Id.*) Furthermore, in his December 11, 2012 telephone call for investors, Berman said: "This particular product is not a generic product. It's an alternative product, and as a result of that, of it [not] being a generic product, it was independently developed and independently designed and independently tested." (Exhibit 4 at 31-32.)

Injury to Johnson & Johnson and LifeScan

79. The GenStrip product is only cleared for sale to owners of specified LifeScan OneTouch Ultra meters. Thus, GenStrip consumers will necessarily consist *exclusively* of consumers who use or will use OneTouch Ultra meters – consumers who rely on the accuracy and ease of use of the OneTouch Ultra system to maintain their health, and with whom LifeScan has built enormous goodwill over the years.

80. Defendants' false advertising and misappropriation of Plaintiffs' trademarks and trade dress will cause irreparable damage to LifeScan's reputation and goodwill.

81. By falsely implying that LifeScan endorses the GenStrip product, Defendants cause Plaintiffs to lose their exclusive control over the LifeScan, OneTouch, and OneTouch Ultra trademarks, along with the distinctive trade dress of OneTouch UltraMini meter.

82. Further, because of Defendants' false claim that LifeScan endorses the GenStrip product, consumers who experience problems or dissatisfaction with GenStrip after its launch will associate those problems and dissatisfaction with LifeScan. This would be devastating

to LifeScan's business, which is built on LifeScan's reputation for accuracy, reliability, and ease of use.

83. Consumer dissatisfaction is likely for several reasons. First, as described above, Defendants are falsely advertising which Ultra meters have been cleared for use with the GenStrip. Second, because customers have become accustomed to a single, preset calibration code and to the ease and convenience of not having to reset it, they would have to be trained and reminded to calibrate when using the Shasta GenStrip. If they were not trained to do so, they could blame LifeScan for any inaccurate test results, further injuring the goodwill associated with LifeScan's products.

84. Shasta, which has never sold a product, has no goodwill or reputation to protect. Instead of risking its own reputation, Shasta risks LifeScan's well-deserved goodwill by falsely implying LifeScan's endorsement of GenStrips.

85. Defendants' false advertising and misappropriation of Plaintiffs' trademarks and trade dress will also allow them to unfairly gain market share, at LifeScan's expense, by trading on the goodwill currently associated with those trademarks and trade dress.

86. In a May 24, 2011 "sales guidance," DDC estimated that GenStrip would have sales of over $170 million in the United States in its first year, and that sales would sharply increase thereafter.

87. These sales would come at LifeScan's expense and would have a crippling effect on LifeScan's business.

88. In addition, LifeScan would have to sharply lower its prices to compete with a supposedly "comparable" test strip that is being sold at a much lower price. Once LifeScan does so, it will be difficult or impossible to raise the price to earlier levels, even if the GenStrip eventually is removed from the market. Trying to raise prices to earlier levels would cause consumer anger and resentment.

89. As a result, LifeScan would lose its position as the market leader, a position LifeScan has worked hard to earn. This position enhances LifeScan's reputation for trust, accuracy,

and quality. Losing its market leadership position would further damage the brand equity that LifeScan has worked hard for many years – and invested millions of dollars – to create and maintain.

FIRST CLAIM FOR RELIEF

Lanham Act – False Advertising

90. Plaintiffs repeat and reallege each and every allegation contained above as if the same were set forth at length herein.

91. On information and belief, Defendants intend to offer their GenStrip product in interstate commerce, and will begin to do so imminently.

92. As set forth above, Defendants' advertising in connection with the Shasta GenStrip constitutes use in commercial advertising or promotion, in interstate commerce, of false and/or misleading descriptions of fact that misrepresent the characteristics and qualities of Plaintiffs' goods and Defendants' good in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

93. In particular, Defendants falsely state or imply that the Shasta GenStrip can be used with *all* OneTouch Ultra meters; that it can specifically be used with the OneTouch UltraSmart meter; that it can be used with OneTouch Ultra meters purchased after July 2010; that the Shasta GenStrip displays "increased accuracy"; and that the Shasta GenStrip is a "generic" product.

94. These false and/or misleading descriptions of fact actually deceived or tended to deceive, and will continue to deceive or tend to deceive, a substantial number of consumers of glucose monitoring systems, and are material to consumers' purchasing decisions.

95. On information and belief, Defendants have engaged in this conduct knowingly, willfully, with malice, and in bad faith.

96. Defendants' activities described above have caused – and will continue to cause – irreparable harm to Plaintiffs, in the form of damage and injury to their business, reputation, and goodwill, for which Plaintiffs have no adequate remedy at law.

SECOND CLAIM FOR RELIEF

Lanham Act – False Endorsement

97. Plaintiffs repeat and reallege each and every allegation contained above as if the same were set forth at length herein.

98. As set forth above, the image of the OneTouch UltraMini meter used in Defendants' promotional material infringes on Plaintiffs' distinctive and non-functional trade dress, which carries secondary meaning.

99. Defendants' use of this image, along with Defendants' other conduct discussed above, in connection with Defendants' promotion of the Shasta GenStrip in interstate commerce, is likely to cause confusion, mistake, or deception as to the source, origin, or approval of the Shasta GenStrip, and also constitutes unfair competition, in violation of the Lanham Act, 15 U.S.C. § 1125(a).

100. Additionally, Defendants' activities are intended to deceive, and are likely to lead members of the public to conclude, incorrectly, that the Shasta GenStrip is manufactured, authorized, licensed, authenticated, and/or endorsed by LifeScan, to the damage and harm of Plaintiffs and the public.

101. Additionally, Defendants' activities are likely to lead members of the public to conclude, incorrectly, that Defendants are affiliated, connected, and/or associated with LifeScan, to the damage and harm of Plaintiffs and the public.

102. On information and belief, Defendants have engaged in this conduct knowingly, willfully, with malice, and in bad faith.

103. Defendants' activities described above have caused – and will continue to cause – irreparable harm to Plaintiffs, in the form of damage and injury to their business, reputation, and goodwill, for which Plaintiffs have no adequate remedy at law.

THIRD CLAIM FOR RELIEF

Lanham Act – Infringement of Registered Trademark

104. Plaintiffs repeat and reallege each and every allegation contained above as if the same were set forth at length herein.

105. The names "OneTouch," "OneTouch Ultra," "OneTouch UltraMini," and "LifeScan," when used in connection with blood glucose monitors and test strips, are protected registered trademarks owned by Johnson & Johnson or LifeScan.

106. Defendants have used in commerce, without Plaintiffs' permission, these marks in a manner that is likely to cause confusion or mistake and to deceive purchasers as to the affiliation, connection, or association of LifeScan with Defendants and/or their products.

107. Defendants' acts constitute infringement of these marks under 15 U.S.C. § 1114.

108. On information and belief, Defendants have engaged in this conduct knowingly, willfully, with malice, and in bad faith.

109. Defendants' activities described above have caused – and will continue to cause – irreparable harm to Plaintiffs, in the form of damage and injury to their business, reputation, and goodwill, for which Plaintiffs have no adequate remedy at law.

FIFTH CLAIM FOR RELIEF

False Advertising Under State Law

110. Plaintiffs repeat and reallege each and every allegation contained above as if the same were set forth at length herein.

111. Defendants' acts, as described above, constitute false and misleading advertising pursuant to Cal. Bus. & Prof. Code § 17500 *et seq.*

112. On information and belief, Defendants have engaged in this conduct knowingly, willfully, with malice, and in bad faith.

113. Defendants' activities described above have caused – and will continue to cause – irreparable harm to Plaintiffs, in the form of damage and injury to their business, reputation, and goodwill, for which Plaintiffs have no adequate remedy at law.

SIXTH CLAIM FOR RELIEF

Unfair Competition Under State Law

114. Plaintiffs repeat and reallege each and every allegation contained above as if the same were set forth at length herein.

115. Defendants' acts, as described above, have impaired and, absent injunctive relief, will continue to impair the goodwill in the OneTouch UltraMini trademark and trade dress, and have otherwise adversely affected Plaintiffs' business and reputation by use of unfair business

practices and false association. These acts constitute unfair competition and unfair business practices under Cal. Bus. & Prof. Code § 17200 *et seq.*

116. On information and belief, Defendants have engaged in this conduct knowingly, willfully, with malice, and in bad faith.

117. Defendants' activities described above have caused – and will continue to cause – irreparable harm to Plaintiffs, in the form of damage and injury to their business, reputation, and goodwill, for which Plaintiffs have no adequate remedy at law.

PRAYER

WHEREFORE, in consideration of the foregoing, Plaintiffs respectfully pray that this Court:

1. Enter a judgment against Defendants in that they have:

(a) Engaged in false advertising under 15 U.S.C. § 1125(a).

(b) Engaged in false endorsement under 15 U.S.C. § 1125(a).

(c) Engaged in trademark infringement under 15 U.S.C. § 1114.

(d) Engaged in false advertising under Cal. Bus. & Prof. Code § 17500 *et seq.*; and

(e) Engaged in unfair competition under Cal. Bus. & Prof. Code § 17200 *et seq.*

2. Grant a preliminary injunction and thereafter a permanent injunction against Defendants and any of their officers, directors, agents, servants, employees, successors, assigns, and attorneys, as well as all of those in active concert or participation with them, with notice thereof, enjoining and restraining all of them from the following:

(a) Using any image of a LifeScan blood glucose meter on the package, package insert or label of the Shasta GenStrip;

(b) Using any image of a LifeScan blood glucose meter in any advertising for the Shasta GenStrip, including any website associated with the GenStrip product;

(c) Using the name of any OneTouch Ultra glucose monitoring device, set out in the distinct font and style used on OneTouch Ultra products, on any package, label, package insert or advertising, including any website associated with the

Shasta GenStrip product;

(d) Stating on the Shasta GenStrip package, label, package insert or advertising (including websites) that the Shasta GenStrip is cleared for use with any OneTouch Ultra blood glucose meters other than OneTouch® Ultra®, Ultra®2, and UltraMini® meters purchased before July 2010;

(e) Failing to include a prominent disclaimer on the package, label, package insert or advertising (including websites) for the ShastaGenStrip that the GenStrip is compatible only with meters purchased before July 2010;

(f) Using the name of any OneTouch Ultra blood glucose meter on the package, label, package insert or advertising (including websites) for the ShastaGenstrip without including an express disclaimer that LifeScan and Johnson & Johnson are not affiliated with Shasta and do not endorse the GenStrip;

(g) Using any Johnson & Johnson or LifeScan trademark on the package, label, package insert or advertising (including websites) for the Shasta GenStrip, except to simply name the meters with which GenStrip has been cleared for use; and

(h) Using the name GenStrip in any manner that falsely suggests that the product is a generic equivalent to the LifeScan products.

3. Order Defendants to recall any Shasta GenStrip products already shipped.

4. Order Defendants to disseminate, in a form to be approved by the Court, advertising designed to correct the false and misleading claims made by Defendants in their advertising.

5. Order Defendants to file with the Court and serve on Plaintiffs within thirty days after issuance of an injunction a report in writing and under oath setting forth in detail the manner and form in which they have complied with the injunction, pursuant to 15 U.S.C. § 1116.

6. Issue an order awarding Plaintiffs monetary relief from Defendants in an amount to be determined at trial, including

(a) All profits received by Defendants from sales and revenues of any kind made as a result of its unlawful actions, this amount to be trebled;

(b) All damages sustained by Plaintiffs as a result of Defendants' actions, this amount to be trebled;

(c) The costs of the action; and

(d) All reasonable attorneys' fees pursuant to 15 U.S.C. § 1117, because of the exceptional nature of this case resulting from Defendants' deliberate and willful conduct;

7. Grant Plaintiffs all other relief to which they are entitled and such other or additional relief as is just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on each of their claims for relief triable before a jury.

Dated: December 14, 2012

By: Susan Roeder

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Attorneys for Plaintiffs
LIFESCAN, INC. and
JOHNSON & JOHNSON

EXHIBIT 1

Decision Diagnostics Corp.

Introducing Genstrip

Blood Glucose Test Strip

For use with Lifescan One Touch® Ultra®, Ultra 2®, Ultra Smart® and Ultra Mini® meters

Frequent and accurate testing of blood glucose is essential to the treatment of diabetes. Unfortunately, high costs of testing supplies puts regular monitoring out of reach for many diabetics.

Shasta's GenStrip® Blood Glucose Test Strips make blood glucose testing fast, easy, convenient, and more affordable for anyone living with diabetes. This new diagnostic product will be comparable to the existing consumable provided by the platform manufacturer, but priced significantly (50%) lower.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 30, 2012

Shasta Technologies, LLC
c/o Mr. Mark DuVal
1820 Medical Arts Building
825 Nicollet Mall
Minneapolis, MN 55402

Re: k103542
Trade/Device Name: Gen Strip Test Strips
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: November 7, 2012
Received: November 8, 2012

Dear Mr. DuVal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k103542

Device Name: GenStrip™ Test Strip

Indications for Use:

GenStrip™ Test Strips with calibration codes 4, 10, and 13 are for use with OneTouch® Ultra®, Ultra®2 and UltraMini® Meters purchased before July 2010. They are used to quantitatively measure glucose in fresh capillary whole blood samples taken from the finger, forearm or palm. Testing is done outside the body (in vitro diagnostic use). They are indicated for use by people with diabetes in their home as an aid to monitor the effectiveness of diabetes control. The system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

Prescription Use _____ And/Or Over the Counter Use _xx_
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k103542

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Site Map

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residenceware

Products

pharmacuetical products
Shasta GenStrip
GenStrip Support

Company Info

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EXHIBIT 2

Int. Cls.: 5 and 10

Prior U.S. Cls.: 6, 18, 26, 39, 44, 46, 51, and 52

United States Patent and Trademark Office

Reg. No. 3,442,347

Registered June 3, 2008

TRADEMARK
PRINCIPAL REGISTER

ULTRAMINI

JOHNSON & JOHNSON (NEW JERSEY CORPORATION)
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 089337001

FOR: TEST STRIPS FOR BLOOD GLUCOSE MONITORING DEVICES, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 9-7-2006; IN COMMERCE 9-7-2006.

FOR: BLOOD GLUCOSE MONITORING DEVICES, IN CLASS 10 (U.S. CLS. 26, 39 AND 44).

FIRST USE 9-7-2006; IN COMMERCE 9-7-2006.

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

OWNER OF U.S. REG. NOS. 2,538,364, 2,730,626, AND OTHERS.

SN 78-647,304, FILED 6-9-2005.

HEATHER THOMPSON, EXAMINING ATTORNEY

Int. Cls.: 5 and 10

Prior U.S. Cls.: 6 and 44

United States Patent and Trademark Office

Reg. No. 1,484,999

Registered Apr. 19, 1988

TRADEMARK
PRINCIPAL REGISTER

ONE TOUCH

JOHNSON & JOHNSON (NEW JERSEY CORPORATION)
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 089337001

FOR: IN VITRO DIAGNOSTIC REAGENT TEST STRIPS USED BY DIABETICS TO TEST THEIR BLOOD GLUCOSE LEVELS, IN CLASS 5 (U.S. CL. 6).
FIRST USE 7-31-1987; IN COMMERCE 7-31-1987.

FOR: HAND-HELD DIAGNOSTIC BLOOD TESTING DEVICE USED BY DIABETICS TO TEST THEIR BLOOD GLUCOSE LEVELS, IN CLASS 10 (U.S. CL. 44).
FIRST USE 7-31-1987; IN COMMERCE 7-31-1987.

SER. NO. 678,981, FILED 8-17-1987.

MICHAEL A. SZOKE, EXAMINING ATTORNEY

Int. Cls.: 5 and 10

Prior U.S. Cls.: 6, 18, 26, 39, 44, 46, 51, and 52

United States Patent and Trademark Office

Reg. No. 2,863,393

Registered July 13, 2004

TRADEMARK
PRINCIPAL REGISTER

ONETOUCH

JOHNSON & JOHNSON (NEW JERSEY CORPORATION)

ONE JOHNSON & JOHNSON PLAZA

NEW BRUNSWICK, NJ 089337001

FOR: TESTS STRIPS USED FOR BLOOD GLUCOSE MONITORING, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 1-15-2001; IN COMMERCE 1-15-2001.

FOR: BLOOD GLUCOSE MONITORING DEVICES AND PARTS AND ATTACHMENTS THEREFORE, IN CLASS 10 (U.S. CLS. 26, 39 AND 44).

FIRST USE 1-15-2001; IN COMMERCE 1-15-2001.

OWNER OF U.S. REG. NOS. 1,484,999 AND 2,538,658.

SN 76-455,402, FILED 9-27-2002.

JEFF DEFORD, EXAMINING ATTORNEY

Int. Cls.: 5 and 10

Prior U.S. Cls.: 6, 18, 26, 39, 44, 46, 51 and 52

United States Patent and Trademark Office

Reg. No. 3,642,309

Registered June 23, 2009

TRADEMARK
PRINCIPAL REGISTER

ULTRA

JOHNSON & JOHNSON (NEW JERSEY CORPORATION)
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 089337001

FOR: TEST STRIPS AND CONTROL SOLUTIONS FOR USE IN GLUCOSE MONITORING, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 1-15-2001; IN COMMERCE 1-15-2001.

FOR: BLOOD GLUCOSE MONITORS, IN CLASS 10 (U.S. CLS. 26, 39 AND 44).

FIRST USE 1-15-2001; IN COMMERCE 1-15-2001.

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

OWNER OF U.S. REG. NOS. 2,538,658, 3,402,295 AND OTHERS.

SER. NO. 77-510,840, FILED 6-30-2008.

ERNEST SHOSHO, EXAMINING ATTORNEY

Int. Cls.: 1, 9 and 10

Prior U.S. Cls.: 6, 26 and 44

United States Patent and Trademark Office

Reg. No. 1,384,863

Registered Mar. 4, 1986

TRADEMARK
PRINCIPAL REGISTER

LIFESCAN

LIFESCAN INC. (CALIFORNIA CORPORATION)
1025 TERRA BELLA AVENUE
MOUNTAIN VIEW, CA 94043

FOR: REAGENT TEST STRIPS USED IN TESTING FOR GLUCOSE IN BLOOD, IN CLASS 1 (U.S. CL. 6).

FIRST USE 6-9-1981; IN COMMERCE 6-9-1981.

FOR: LABORATORY EQUIPMENT, NAMELY, BLOOD GLUCOSE MEASURING METERS , IN CLASS 9 (U.S. CLS. 26 AND 44).

FIRST USE 6-9-1981; IN COMMERCE 6-9-1981.

FOR: FINGER PRICKING DEVICES USED TO DRAW BLOOD FOR MEDICAL USE, IN CLASS 10 (U.S. CL. 44).

FIRST USE 6-9-1981; IN COMMERCE 6-9-1981.

SER. NO. 504,694, FILED 10-19-1984.

LARRY BAUMAN, EXAMINING ATTORNEY